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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,206	07/29/2003	Kei Roger Aoki	17328CON4	1996
<div>7590 Stephen Donovan Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612</div>			<div>EXAMINER KAM, CHIH MIN</div>	
			<div>ART UNIT 1656</div>	<div>PAPER NUMBER</div>
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/01/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/630,206

Applicant(s)

AOKI ET AL.

Examiner

Chih-Min Kam

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1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,9,12,13,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9,12,13,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 4, 5, 9, 12, 13, 31 and 32 are pending.

Applicants' amendment filed November 17, 2006 is acknowledged, and applicants' response has been fully considered. Claims 1, 12 and 31 have been amended. Thus, claims 1, 4, 5, 9, 12, 13, 31 and 32 are examined.

### **Withdrawn Claim Rejections - 35 USC § 102**

2. The previous rejection of claims 1, 4, 5, 9, 12, 13, 31 and 32 under 35 U.S.C. 102(b) as being anticipated by Binder (WO 95/30431), is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 4 in the amendment filed November 17, 2006.

### ***Claim Objections***

3. Claim 1 is objected to because of the use of the term ".....to the face of a mammal with a face pain is not due to a headache". Use of the term ".... to the face of a mammal with a face pain, wherein the face pain is not due to a headache". See also claims 12 and 31.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4, 5, 9, 12, 13, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 4, 5, 9, 12, 13, 31 and 32 are directed to a method of treating or alleviating a face pain, the method comprising the step of peripheral administration of a therapeutically effective amount of a botulinum toxin to the face of a mammal with a face pain, wherein the face pain is not due to a headache, wherein the peripheral administration is carried out by intramuscular administration of the botulinum toxin, and wherein the face pain is not associated with a muscle disorder. While the specification indicates that the present invention provides an effective, long lasting, non-surgical method to treat pain, particularly pain which is not associated with a muscle disorder or headache (page 19, line 27 to page 20, line 1), and a patient with nasopharyngeal tumor type pain (having pain in the lower left cheek; face pain) is treated by a bolus injection of about 10-35 units of botulinum toxin type A intramuscularly to the cheek (Example 4), the specification does not disclose the use of a botulinum toxin to treat various types of face pain, e.g., trigeminal neuralgia (see attached definition) or atypical facial neuralgia is also a face pain, not due to a headache or associated with a muscle disorder. A single species of face pain (i.e., nasopharyngeal tumor type pain) to be treated does not provide written description for various types of face pain in the claimed method. The lack of description on the treatment of various types of facial pain using the botulinum toxin and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C<sub>1</sub>, D, E, F and G" in lines 1-3. There is insufficient antecedent basis for this limitation in the claim because the independent claim (claim 12) only recites botulinum toxin type A.

***Conclusion***

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

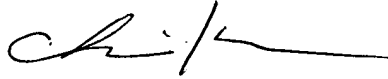
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chih-Min Kam, Ph. D.  
Primary Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min', followed by a long horizontal stroke.

CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

January 23, 2007